UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA
***ex rel.* WENDY A. BAHNSEN et al.**

Plaintiffs,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,

Defendant.

Honorable Susan D. Wigenton

Civil Action No. 11-cv-1210

RELATORS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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I. INTRODUCTION

The False Claims Act ("FCA") allows private persons to file suit for violations of the FCA on behalf of the government (qui tam "Relators"). The FCA establishes a civil cause of action for the recovery of damages, and penalties, from those who submit false or fraudulent claims to the United States. To establish a prima facie case under the false claims prong of the FCA, the relator must prove: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. 31 U.S.C. § 3729; *Landau v. Lucasti*, 680 F. Supp. 2d 659, 665 (D.N.J. 2010).

This False Claims Act action was brought by Wendy Bahnsen ("Bahnsen") and Carolina Fuentes ("Fuentes") (collectively, the "Relators"), who, while employed by Defendant Boston Scientific Neuromodulation Corporation ("Boston Scientific," the "Company" or "Defendant"), witnessed acts of Medicare and Medicaid fraud being committed by the Company. Relators complained about the fraudulent conduct in an effort to alert the Company's management to stop its unlawful conduct. Instead of acting to address the Relators' complaints of fraud, Boston Scientific unlawfully retaliated against the Relators.

The Relators allege the Defendant violated the False Claims Act to maximize reimbursement from Medicare and Medicaid by: (1) submitting claims

misrepresenting that the Defendant was in possession of a physician's order required for payment of such claims; (2) making up or changing diagnosis codes on Medicare claim forms; (3) submitting Medicare claims without knowing whether supplies were medically necessary; (4) concealing patient harm from the government that involved defective equipment, then improperly submitting claims to Medicare; (5) paying kickbacks to artificially increase sales of its expensive medical devices; and (6) falsely certifying its compliance with laws that go to the heart of Defendant's role as a medical equipment supplier to Medicare patients. (*See* First Amended Complaint, or "FAC" ¶¶ 23, 58-61).

After trying to stop the Company's unlawful practices, Relators were disciplined. (FAC ¶144.). When Relators refused to be silenced, Bahnsen was summarily and unlawfully terminated from her employment and Fuentes was subjected to a hostile work place. (FAC ¶¶144, 154, 161 and 163). In its Motion to Dismiss, Boston Scientific employs a "kitchen sink" approach to Relators' fraud claims, premised upon its selective reading of the FAC as well as its misreading of the applicable law and the FCA.

Together with Defendant's other Motions, the Motion to Dismiss should be denied.

II. FACTUAL BACKGROUND

Relator Wendy Bahnsen possesses specialized background and knowledge of Medicare compliance requirements. She is an experienced medical biller, who was employed first in the Company's Customer Service Department, until she was promoted to the Billing and Collections Department. (FAC ¶ 8). In Customer Service, her primary task was to coordinate and resolve adverse issues patients were experiencing with Boston Scientific's Precision Plus™ spinal cord stimulation system, such as technical or device problems, lead migration, skin irritation, burns and infection. *Id.*

Then from January 2009 through her date of termination, Bahnsen was employed in Boston Scientific's Billing and Collections Department as a Reimbursement and Claims Management Specialist. (FAC ¶ 9). Her primary task was to submit claims for payment to Medicare, Medicaid and private insurance companies to obtain payment for Boston Scientific's medical equipment supplies associated with Boston Scientific's spinal cord stimulation medical devices. *Id.*

Relator Fuentes was employed by the Defendant from May 2005 through June 2010. She was first employed as the Administrative Assistant to the Vice President of Health Economics and Reimbursement, John Hernandez, from May 2005 through March 2008. (FAC ¶ 13). Relator Fuentes was then transferred to the Billing and Collections Department in February 2009, until June 2010. *Id.*

The Relators are classic insiders with personal knowledge of Boston Scientific's fraudulent conduct.

The Defendant is a government contractor – an approved supplier of medical devices and replacement supplies -- which includes the Precision Plus™ Spinal Cord Stimulation ("SCS") system, approved by the FDA in 2004 for use in the treatment of intractable back pain. (FAC ¶ 17). The Precision Plus™ SCS System consists of both the implanted device and external equipment. *Id.* The external equipment includes (1) a wireless remote control, (the Precision SCS Remote, also known as the Programmer); (2) a cordless battery charger, (the Precision Charger); and (3) the Precision Adhesive Kit (26 double-sided adhesive patches used to attach the cordless charger to the patient's implant site). *Id.*

The remote control, known as the Precision™ SCS Remote Model SC-5210, allows the patient to turn stimulation on and off, increase and decrease the level of stimulation, and target different pain areas using programs that are customized for use in different situations. (FAC ¶ 18).

The charger, known as the Precision™ SCS Charger 2.0 Model SC-5312 is a follow-on charger that replaced the Precision Charger 1.0, which was recalled due to defects which caused burns. (FAC ¶ 19). The Precision Charger is a cordless (*i.e.*, wireless) lightweight charger which allows the patient to subcutaneously recharge his/her IPG battery while he/she continues to receive therapy. *Id.* A

patient needs only to place the charger on top of the implant site using an adhesive patch or charging belt provided with the SCS system. *Id.* Since April 2004, numerous patients reported receiving severe burns in the area of charging while using the Precision Charger 1.0. *Id.* Boston Scientific issued a recall of its Precision Charger 1.0 in September of 2008. *Id.*

The adhesive kits, known as the Precision™ Adhesive Kit Model SC-6350, consists of 26 double-sided adhesive patches used to attach a cordless charger to the patient's implant site while their Implantable Pulse Generator ("IPG") battery is being recharged. (FAC ¶ 20).

In 2009, Boston Scientific's Neuromodulation products earned U.S. net sales of $271 million, as compared to $234 million in 2008, which includes amounts paid or reimbursed by federal and state funded Government Programs, including Medicare and Medicaid. (FAC ¶¶ 21-22). As a government contractor providing medical equipment and supplies to Medicare patients, Medicare billing and compliance requirements are binding on the Company, as Defendant readily acknowledges. (*See* Def. Br. at 6-7).

Relators have alleged that Defendant knowingly[1] submitted or caused to be submitted false claims in the marketing of its SCS System, fraudulent billing to

[1] To violate the FCA, a person or entity must have submitted, or caused the submission of, the false claim (or made a false statement or record) with knowledge of the falsity. "Knowledge" is defined as (1) actual knowledge, (2)

obtain government reimbursement for the SCS System's replacement supplies, and false certifications of the Company's compliance with applicable law, which compliance was a condition of payment. (FAC ¶¶ 23-162).

III. RELATORS HAVE STATED A CLAIM UPON WHICH RELIEF CAN BE GRANTED AS TO THEIR FALSE BILLING ALLEGATIONS[2]

In considering a Motion to Dismiss under Fed. R. Civ. P. 12(b)(6), the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)).

Though the recent Supreme Court pleading cases, *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), have caused much debate and discussion, "[n]otwithstanding *Twombly* [and *Iqbal*], the basic tenants of the Rule 12(b)(6) have not changed." *Charleston v. Salon Secrets Day Spa, Inc.*, 2009 U.S. Dist. LEXIS 45638, at *7-8 (E.D. Pa. June 1, 2009). Under the Third Circuit's reading of *Twombly*, "the notice pleading standard of Rule 8(a)(2) remains intact" and although mere "labels and conclusions" will not suffice,

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deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b).

[2] Defendants concede that Relators have sufficiently alleged Defendant's billing fraud as required under Fed. R. Civ. P. 9(b). (*See* Def. Motion to Dismiss at 15, n. 4).

Twombly "does not require 'detailed factual allegations.'" *Phillips*, 515 F.3d at 231, 233; *see also U.S. v. Torkelson*, 2007 U.S. Dist. LEXIS 88955, at *16 n.2 (E.D. Pa. Dec. 3, 2007) ("The Supreme Court in *Twombly* explicitly did not alter or broaden the scope of the Federal Rules of Civil Procedure.").

A. Relators Have Sufficiently Alleged that Defendant Did Not Have Physician Orders Prior to Submitting the CMS-1500 Claim Form to Support Medical Necessity

Defendant misconstrues Relators' allegations in the FAC. Relators simply allege that Medicare claims were submitted to Medicare without a physician's order, i.e. without any evidence of medical necessity. Relators do not allege that any initial order was available. To the contrary, Relators have alleged that no physician orders were available, that the Company instead directed its billing and collection employees to avoid wasting time trying to locate any physician order. (FAC ¶¶ 148-149). Although Defendant agrees with Relators that evidence of medical necessity in the form of a physician order is required as a condition of Medicare reimbursement[3] (*See* Def. Motion to Dismiss at 8), Defendant asserts misplaced arguments as to the need for physican orders to support replacement supplies and inapplicable Medicare guidance, premised on a fundamental

[3] Relators allege that the Medicare statute and regulations specify items or services are only reimbursable when "medically indicated and necessary." *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) ("nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury"). (FAC ¶¶ 43, 48 and 77).

misreading of Relators' allegations. Relators allege that Defendant knowingly submitted claims without any physician orders.[4] (*See e.g.* FAC ¶¶ 23, 31, 34, and 148-149).

These physicians' orders provide the documentation requirements to substantiate that the physician has reviewed the patient's condition and has determined that certain equipment and supplies are medically necessary before a medical supplier like Boston Scientific submits a claim to Medicare. These allegations must be accepted "as true" at this stage of the case. *Iqbal*, 556 U.S. 662.

As to applicable Medicare guidance, Defendants wrongly assert that, once the patient has received the implantable SCS device, follow-up physician orders for replacement supplies are never required.[5] Relators allege that physician orders for replacement supplies are required, and that, the Company acknowledged as much by providing blank order supply forms to physicians to complete. (FAC ¶ ¶ 108, 109).

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[4] The Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, § 5.8 on "Supplier Documentation" states in relevant part: "Before submitting a claim…the supplier must have on file a dispensing order [and] information from the treating physician concerning the patient's diagnosis…" In addition, this documentation must be maintained in the supplier's files for seven (7) years.

[5] Unless a physician has specified on the initial order for the implanted device, the supplies and frequency with which the patient may obtain the supplies, and the Defendant supplier is in possession of this order, a new physician's order may not be needed. *See* Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §§ 5.2.4.

The Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, § 5.2.4[6] supports Relators' allegations:

5.2.4 – Requirement of New Orders

A new order is required in the following situations:

- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
- **When an item is replaced;** and
- When there is a change in supplier. (emphasis added)

The replacement supplies at issue here – remotes, chargers, and adhesive kits – all require a new order, since these items are being "replaced." Defendant was aware of this requirement, as Relators allege, as it was discussed in meetings and when Defendant provided its own physician order forms for these supplies.

The Medicare manual that Defendant cites mischaracterizes the applicable requirements for Medicare suppliers. For example, the Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15 §§ 120(D) and 110.2[7] on which Defendants rely,

[6] Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c05.pdf

[7] Available at:

refers to conditions of coverage, including evidence of medical necessity. Neither section negates a supplier's requirement to obtain physician order for supplies. Quite the contrary. *See* Section 110.2: "A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item." Suppliers are directed to follow the Durable Medical Equipment ("DME") provisions in the Medicare Program Integrity Manual, which as Relators allege and set forth above, requires an order for replacement supplies.

The Medicare program requirement of a new order is logical considering that equipment suppliers like Defendant typically do not have possession of physician orders for related surgically-implanted devices. As Defendant explains, hospitals and physicians submit their own claims, supported by physician orders, to Medicare for the initial implants, in accordance with the Medicare Claims Processing Manual, Pub. 100-04, Ch. 14 § 10.2. (*See* Def. Motion to Dismiss at 6, n. 2). Medicare's regulatory framework therefore recognizes that the supplier of replacement supplies may not know if and when patients need replacement supplies, and thus in order to ensure medical necessity, a new physician order is required to bill Medicare. This is what Relators allege. (FAC ¶ 108).

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http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

Relators have also alleged that a supplier's possession of a physician's order is a condition of payment (FAC ¶ 108); that Defendant itself provided physicians with its own order form entitled "Healthcare Provider's Order For Precision SCS Supplies (FAC ¶ 109); that the need for a physician's order was discussed and acknowledged by Senior Company management; (FAC ¶ 110); and that Defendant nonetheless ignored this requirement in order to unlawfully bill and be reimbursed by Medicare. (FAC ¶¶ 29, 31).

Given that Relators' detailed factual allegations as to these factually and legally false claims must be taken as true, and construed in their most favorable light, Defendant's 12(b)(6) motion as to physician orders must be denied.

B. Relators Have Sufficiently Alleged that Defendant Falsified Diagnosis Codes on CMS-1500 Forms Submitted to the Government

As Defendants acknowledge, Medicare deems valid diagnosis codes material, and requires valid codes for the claims submitted by Defendant. The systematic practice of making up codes renders each of these claims factually false.[8] Relators have alleged that Defendants made up codes without any physician documentation or physician input, in essence, self-diagnosing patients. (FAC ¶¶ 28-35, 38-42, 148-151). The made-up codes were usually several favorite codes,

[8] Valid, accurate diagnosis codes are required. *See* Medicare 100-04, Ch. 23 § 10. *See also* the Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, § 5.8 on "Supplier Documentation" which required Defendant, prior to submitting a claim, to have information from the treating physician concerning the patient's diagnosis.

such as code 724.2 ("lumbago" or back pain), which assured prompt Medicare reimbursement, and was a financial advantage to Defendants. (FAC ¶ 33, 38, 39, 41 and 148-149). Using 724.2, for example, was financially advantageous because of the prevalence of off-label uses (such as phantom leg pain), which would generate a diagnosis code not related to the FDA-approved use associated with back pain. Using back pain-related codes avoided any red flags that could result in denials, questions or audits by Medicare.[9]

In only certain limited circumstances not present here, Medicare allowed Boston Scientific to insert a diagnosis code on the CMS-1500, for example if the physician provided a medical record or a verbal description to the Defendant. However, Relators have alleged that those circumstances were not present. (*See e.g.* FAC ¶¶ 120-124). Here, Relators have amply alleged that Defendant knowingly submitted CMS-1500 claim forms that were materially false. (FAC ¶¶ 28-35, 38-42, 148-151).

[9] Defendant argues that, since these supplies are reimbursed under a Medicare fee schedule, it should benefit from the "no-harm no-foul" defense. However, Defendants ignore circumstances when, for example, the item was not medically necessary, or when Medicare should not have made payment based on Defendant's false claims, or Defendant's violations of conditions of payment.

Moreover, Relators have amply alleged that Defendant made up diagnosis codes, and even in circumstances when it did possess a physician order, changed codes.[10] (FAC ¶¶ 28-35, 38-42, 142, 148-151).

Finally, Defendant's selective reading of Relators' allegations leads it to argue that "[a]t most Relators have alleged that it is conceivable that an error could have been made in the selection of diagnostic codes by [Boston Scientific]…." (*See* Def. Motion to Dismiss at 17). Yet, Relators are not alleging an "inadvertence" scheme. Rather, Relators allege they were trained and directed to make-up codes without consulting any physician or medical record; that when they complained, the Company ignored their concerns; and when the Relators persisted in complaining, the Defendant retaliated against them. (*See* FAC ¶¶ 59, 143, 144, 146, 155, 158, 161, 162 and 163). These allegations do not describe Boston Scientific's commission of an "error," but rather Boston Scientific's knowing and systematic practice of violating the FCA.

[10] Defendants also raise a disputed factual issue not ripe for resolution at this stage of the litigation -- *e.g.*, that Medicare might have paid one or more of the alleged false claims even in the face of Defendant's fraud and violation of Medicare program requirements. Relators have, however, sufficiently alleged that Defendant's submission of its false billing claims was material to the government's decision to pay. (FAC ¶ 47, 51 and 53). Defendant itself acknowledges that "valid" (i.e. true and accurate) diagnosis codes are required for Medicare claims. (Def. Motion to Dismiss at 11).

Given that Relators' detailed factual allegations must be taken as true, and construed in their most favorable light, Defendant's 12(b)(6) motion as to falsified diagnosis codes must be denied.

C. Relators Have Sufficiently Alleged That the Defendant's Pattern and Practice of Falsifying Claim Forms Supports Relators' False Certification Claims

Relators have alleged that, as a Medicare supplier, Defendant was obligated to comply with laws material to its role as a supplier of medical equipment to Medicare patients, and that compliance with these laws was a condition of Medicare payment. (FAC ¶ 100). Relators allege in paragraph 100 that Defendant entered into agreements with the government that required compliance with law as a condition of payment, and quoted the applicable Medicare form:

> "100. To participate in the Medicare program, DME suppliers enter into agreements with CMS in which the supplier agrees to conform to all applicable statutory and regulatory requirements for reimbursement from Medicare. For DME suppliers like [Boston Scientific], a CMS Form 855S (or equivalent) is completed. At all relevant times, [Boston Scientific] was a certified supplier which applied for Medicare enrollment by completing a Form CMS-855. The CMS-855 contains a certification of compliance with law, which further notified [Boston Scientific] that lawful compliance is a condition of payment by Medicare:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare." (emphasis added)

Relators alleged in great factual detail in the First Amended Complaint how Defendant systematically failed to abide by "Medicare laws, regulations and program instructions".[11] Defendant falsely certified its compliance with the law, and at that time and continuing into the future, committed the fraudulent acts, including payment of kickbacks, alleged herein. As such, all payments made from Medicare were wrongly paid.[12]

In addition, Relators have alleged that Defendant falsified numerous CMS-1500 claim forms, and as a result, falsely certified compliance with its legal billing

[11] Defendant's Motion to Dismiss (*e.g.*, at 17) recites factual scenarios and fact-based arguments, such as characterizing the alleged flagrant billing fraud as "acceptable billing practices for suppliers…" These factual arguments are not appropriately considered at the motion to dismiss stage.

[12] 42 C.F.R. pt. 424 "Conditions of Medicare Payment" addresses, *inter alia*, Medicare DME Supplier Standards. These standards include "compliance with all applicable federal and state licensure and regulatory requirements." CMS as well as its Medicare carriers, such as Palmetto GBA, which handled the processing of Defendant's claims (FAC ¶ 118) enforce these standards, which are listed in 42 C.F.R. pt. 424, § 424.57(c). Suppliers must be in compliance with these Supplier Standards in order to obtain and retain their billing privileges. The Palmetto GBA Supplier Standards are located at http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~National%20Supplier%20Clearinghouse~Supplier%20Enrollment~Standards%20Compliance~DMEPOS%20Supplier%20Standards~7GLS7Z1267?open&navmenu=||

obligations by signing each of the false CMS-1500 forms submitted to Medicare. (FAC ¶¶ 47, 142).

These allegations are sufficient that, if true, to establish Defendant's liability on a false certification theory, which has been endorsed by the Third Circuit and every other Circuit to have the issue considered. The Third Circuit takes an expansive view of the remedial purposes of the False Claims Act. *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 306 (3d Cir. 2011) ("[A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation . . . . [Claims made to Medicare or Medicaid programs] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program. . . .").

Taken as a whole and construed in the light most favorable to Relators, Relators' detailed factual allegations in the First Amended Complaint, Relators' false certification claims are more than adequate to survive Defendant's 12(b)(6) motion.

IV. RELATORS HAVE SUFFICIENTLY PLED FALSE CLAIMS RELATED TO DEFECTIVE EQUIPMENT

Relators have more than adequately alleged facts that place the Defendant on notice of the claims against it. Indeed, detailed allegations of the submission of a false claim are not required at the motion to dismiss stage of the proceeding.

Relators have sufficiently pled that Defendant submitted false claims by covering up patient harm, and then submitting claims to Medicare for expensive defective equipment and related surgeries.[13]

Relators have alleged Defendant provides patients with replacement equipment, such as the battery charging system it markets and sells as the Precision SCS Implantable Pulse Generator ("IPG"). (*See eg.* FAC ¶¶ 17, 27). Relators have further alleged that Defendant concealed and/or sought to minimize reports of patient harm, and failed to reimburse Government Programs for defective devices and equipment. (FAC ¶¶ 83-87).

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[13] Relators have met the Third Circuit's flexible Rule 9(b) pleading standards. Under Third Circuit precedent, Rule 9(b) is to be read in tandem with Fed. R. Civ. P. 8(a)(2), which only requires "a short and plain statement of the claim showing that the pleader is entitled to relief." This Court (and other Third Circuit courts) has explicitly stated that the "particularity requirement [of 9(b)] must be read in conjunction with the liberal pleading rule of Fed. R. Civ. P. 8(a)." *Knight v. Rourke*, 1995 U.S. Dist. LEXIS 2919, at *10 (E.D. Pa. Mar. 9, 1995); *United States ex. rel. Landsberg v. Levinson*, 2006 U.S. Dist. LEXIS 66689, at *10 (W.D. Pa. Feb. 13, 2006) (denying motion to dismiss because complaint was "[c]onsistent with the requirements of Rule 9(b) and with Rule 8's requirement of a short, plain statement of entitlement to relief"). Moreover, the requirements of 9(b) are relaxed under the circumstances presented in this case. The requirements of 9(b) are not applied in circumstances when the defendants have control of the factual information. *See, e.g.*, *In re U.S. Bioscience Sec. Litig.*, 806 F. Supp. 1197, 1201 (E.D. Pa. 1992) ("[C]ourts have 'relaxed the [particularity] rule when factual information is peculiarly within the defendant's knowledge or control.'" (citation omitted and alteration in original)). That is because "courts should be 'sensitive' to situations in which 'sophisticated defrauders' may 'successfully conceal the details of their fraud.'" *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp.*, 2009 U.S. Dist. LEXIS 38898, at *14 (D.N.J. May 7, 2009).

Relators have provided detailed allegations as to the manner in which the Company tracked patient complaints. See FAC ¶ 56: "[Boston Scientific] tracked these patient issues by entering Customer Service call notes with sales representatives and patients into [Boston Scientific]'s 'Net Regulus' computer program. These calls are recorded by [Boston Scientific]." Relators allege the range of patient complaints experienced with the implantable device, as well as certain external supplies. (FAC ¶ 57). Relators allege that the time frame involved was at least March 31, 2008 to January 2009. (FAC ¶ 56). Relators identified as an example an "Issue Detail Report" dated September 29, 2009 involving a patient who was burned by a defective charger. (FAC ¶ 70). The patient's complaint was entered into the Defendant's Net Regulus system as "Record No. 369,126." (FAC ¶ 82). Relators further allege that, since the defective charger was out of warranty, a manager pushed replacement off on to the patient's insurance company. (FAC ¶ 71). The insurance company was likely Medicare. (FAC ¶ 72). The defect was either in the implanted device, or the charger, and as a result, the device needed to be surgically "explanted." (FAC ¶ 72).

Relators have alleged Defendant's obligations under federal law related to adverse event reporting for medical devices. (FAC¶ 62-64). In order to avoid legally required reporting of certain adverse events, Defendant's Customer Service Employees were required to manipulate how patient complaints were recorded.

(FAC ¶¶ 73-76). The known defects associated with certain of Defendant's devices and equipment rendered them not reasonable and necessary and thus ineligible for reimbursement. (FAC ¶ 85). Finally, Relators allege the submission of false claims to Medicare. (FAC ¶ 87).

As to Relators' allegations that Defendant ignored its responsibility to report patient adverse events to proper government authorities, and to shoulder the financial burden for defective equipment (and associated surgeries), Relators have met the generous pleading standards in the Third Circuit. *See United States ex rel. Singh v. Bradford Regional Med. Ctr.*, 2006 U.S. Dist. LEXIS 65268, at *12 (W.D. Pa. Sept. 13, 2006) (holding that pleading fraudulent scheme can survive 9(b) "without requiring specific identification of claims"); *Landsberg*, 2006 U.S. Dist. LEXIS 66689, at *8-10 (holding that "Relators have sufficiently identified the scheme of fraudulent behavior" and that Third Circuit approach does not "requir[e] the plaintiff to plead the facts of each individual claim, particularly where the claims are numerous and extend over the course of several years")

Under Third Circuit precedent, consistent with its generous approach to the pleading requirements of 9(b), to survive a motion to dismiss a plaintiff/relator only needs to detail the general fraudulent scheme that led to the submission of false claims, which Relators have done here.

V. RELATORS' ADVERSE EVENT CLAIMS ARE NOT BARRED BY

THE PUBLIC DISCLOSURE DOCTRINE

A. Relators' Allegations Are Not Barred By the Public Disclosure Doctrine

Defendant makes a cursory argument that Relators' allegations of fraudulent underreporting of adverse event reports ("AERs") are barred pursuant to the public disclosure doctrine. This argument has no merit. Relators' allegations of the systematic underreporting of AERs are not based upon the alleged public disclosures that Defendant attached to its Motion. To hold otherwise – where Defendant has attached only two "confidential" letters it submitted to the FDA containing sparse and vague references to review criteria for the Precision Plus SCS System – would be an inappropriate expansion of the public disclosure bar. (*See* Def. Mem. of Law Ex. 1-2). There is no justification to find these two letters publicly disclosed the systematic fraud concerning the intentional underreporting of AERs for the Precision Plus SCS System.

The public disclosure bar is designed as a "balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, ___ U.S. ___, 130 S. Ct. 1396, 1407 (2010). To trigger the bar, a relator's allegations need to be "based upon" public disclosures stemming from one of the enumerated sources contained in § 3730(e)(4)(A)(i)-(iii). Allegations are considered "based upon" a qualifying public disclosure only if they are "supported by or substantially similar

to the [publicly] disclosed allegations and transactions." *United States ex rel. Atkinson v. PA Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007).

Here, it is clear that Defendant's two letters do not trigger the public disclosure bar. The contents of the letters are not a public disclosure for a simple reason: they were not publicly disclosed. *See United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332-33 (3d Cir. 2005) (holding that "to qualify as a public disclosure under the FCA, a disclosure must (1) issue from a source or occur in a context specifically recognized by the Act, and (2) be sufficient to support the conclusion that the information contained therein is now public within the meaning of the Act").

The two letters that Defendant voluntarily submitted to the FDA were not publicly disclosed. The headers on each letter are denoted in bold print that they are "confidential." (*See* Def. Mem. of Law Ex. 1-2). Moreover, because each letter contained confidential information and trade secrets, Defendant requested from the FDA that the letters "not be publicly disclosed prior to thorough redaction of such information." *See id.* Nowhere in its motion does Defendant claim that these letters were subsequently disclosed to the public. At most, ***these letters represent direct communications between Defendant and the FDA*** regarding the Defendant's general handling of complaints and MDR systems, with a brief mention of reporting complaints related to the Precision Plus SCS System.

However, a confidential communication with the FDA does not amount to a public disclosure. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 728 (1st Cir. 2007) (holding that "self–disclosure made by private party only to government agencies, without further disclosure . . . does not itself constitute public disclosure"). Instead, to qualify as a public disclosure, "there [must] be some act of disclosure to the public outside of the government." *Id.*[14]

Defendant attempts to bootstrap its position because the supplemental AERs that Defendant submitted to the FDA are available to the public through a FOIA request. (*See* Def. Mem. of Law at 24 n.7). This in and of itself, however, does not amount to a public disclosure. Nor does Defendant argue that Relators submitted a FOIA request. *See United States ex rel. Mistick PBT v. Housing Auth. of the City of Pittsburgh*, 186 F.3d 376, 383 n.3 (3d Cir. 1999) (holding that

[14] The *Rost* Court also observed that "[i]f providing information to the government were enough to trigger the bar, the phrase 'public disclosure' would be superfluous." 507 F.3d at 729. The same conclusion has likewise been reached in: *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1201 (9th Cir. 2009) ("Thus, even when the government has the information, it is not publicly disclosed under the Act until it is actually disclosed to the public."); *Kennard v. Comstock Res. Inc.*, 363 F.3d 1039, 1043 (10th Cir. 2004) (concluding that "the Government is not the equivalent of the public domain"); *United States ex rel. Williams v. NEC Corp.*, 931 F.2d 1493, 1496 (11th Cir. 1991) ("Even if a government investigation was pending at the time [relator] filed his *qui tam* complaint, such fact would not jurisdictionally bar [relator] from initiating suit under the FCA."); *United States ex rel. Whitten v. Cmty. Health Sys., Inc.*, 575 F. Supp. 2d 1367, 1381 (S.D. Ga. 2008) (holding that the jurisdictional bar did not apply where there was "no evidence that any information about the [Government's] investigation was ever revealed to the public.").

"information may be easily accessible to the public – it may be available under FOIA to anyone who simply files a request – but unless there is a request and the information is actually produced, it is not publicly disclosed"). Moreover, the availability of AERs themselves on the FDA website or through a FOIA request would not in any way reveal Defendant's intentional fraudulent scheme to systematically underreport AERs. Thus, the mere public availability of AERs would not publicly disclose anything that would allow a third-party to conclude that a fraud has been committed. In other words, the allegations in the FAC are not "based upon" the alleged public disclosures contained in the AERs.[15]

[15] Furthermore, even assuming that the letters themselves (as opposed to just the AERs) were disclosed to others outside the Government, they would still not be qualifying public disclosures, because they too fail the Third Circuit's "based upon" formulation. It strains credulity to believe that Relators' allegations in the Complaint are based on (*i.e.*,, supported by or substantially similar to) the two letters from Defendant to the FDA. These letters contain nothing more than a few stray general statements related to its intake procedure for complaints about the Precision Plus SCS System. And one of the letters states that, based on its own internal review, Defendant would submit approximately 500 additional AERs. (*See* Def. Mem. of Law Ex. 1-2). Nowhere are there any statements that would lead a stranger to read these letters and be able to infer a systematic fraud has been committed, nor are there statements that would put the DOJ squarely on the trail of fraud. In fact, it is quite the opposite. These letters contain carefully crafted statements from Defendant to downplay any potential wrongdoing. Thus, the plain fact is that these letters do not qualify as public disclosures sufficient to implicate the jurisdictional bar.

B. Relators Are Original Sources

Defendant's public disclosure arguments fail. Regardless, whether there was a qualifying public disclosure is irrelevant. That is because Relators qualify as original sources. *See* 31 U.S.C. § 3730(e)(4)(A) (noting that relator is not barred from bringing suit even if based on public disclosures if relator is "an original source of the information"). This doctrine is only "intended to avoid parasitic lawsuits by 'disinterested outsiders' who 'simply stumble across an interesting court file.'" *United States ex rel. Barth v. Ridgedale Elec.*, 44 F.3d 699, 703 (8th Cir. 1995). It is not meant to prohibit legitimate insiders who have useful information about fraud being committed against the Government from bringing False Claim Act cases. Indeed, the Third Circuit has recognized that "[t]he paradigmatic 'original source' is a whistleblowing insider." *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991). And that is exactly the scenario that is presented here.

Under the new version of the rule, a relator is an original source if he or she: "(i) prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, ***or*** (ii) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transaction, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(3)(4)(B)

(emphasis added). Here, Relators' independent knowledge of material facts more than passes this threshold.

To have independent knowledge "mean[s] that knowledge of the fraud cannot be merely dependent on a public disclosure." *Paranich*, 396 F.3d at 336. From March 2008 through January 2009, Relator Bahnsen was employed in Defendant's Customer Service Department. (*See* FAC ¶ 56). In this position, she dealt directly with customers alleging defects with Defendant's products, including the Precision SCS System. In addition, she was directly trained by her supervisors to "avoid documenting patient adverse events or device problems." (FAC ¶ 59). Thus, there is no question that Relator Bahnsen's knowledge came from her own exposure to Defendant's systematic underreporting of AERs and not from the alleged public disclosures contained in Defendant's two letters to the FDA. *See Paranich*, 396 F.3d at 337 (finding relator had independent knowledge because "his initial knowledge was, from his own experience, independent of such [public] disclosures").

Defendant's alleged public disclosures contained in two letters to the FDA make no mention of a systematic fraudulent scheme to underreport AERs. It is Relators' allegations that shed the true light on the AERs in relation to Defendant's fraud, and explain that there had been concerted effort placed on staff to inaccurately report patient complaints to avoid reporting those to the FDA.

And Defendant's cursory argument that Relators' FAC does not detail this material information with adequate specificity cannot be credited. (*See* Def. Mem. of Law at 25). On the contrary, Relators' FAC contains over 30 paragraphs detailing the scheme with specificity. (*See* FAC ¶¶ 55-87). Relators detail how Relator Bahnsen was directed to conceal any references to burns in her calls with complaining patients in order to avoid FDA reporting. (*See* FAC ¶¶ 59, 68 and 75-76).

Relators have also sufficiently alleged that they provided the Government with information prior to filing the First Amended Complaint. (*See* FAC ¶¶ 11-12, 14-15). Thus, Relators satisfy the original source exception and have standing to bring this FCA claim.

VI. RELATORS HAVE SUFFICIENTLY ALLEGED A KICKBACK SCHEME THAT RESULTED IN DEFENDANT'S FALSE CERTIFICATIONS OF COMPLIANCE

Relators have sufficiently alleged under applicable Third Circuit standards that Defendant engaged in an unlawful kickback scheme involving on-label, as well as off-label, conduct to increase utilization of its SCS system.[16]

[16] Defendant devotes a significant amount of time defending their practice of promoting the SCS System for non-FDA approved uses. (*See* Def. Motion to Dismiss at 26-30). Relators' have alleged illegal off-label promotion in conjunction with Defendant's illegal kickbacks in a scheme to artificially increase utilization of its SCS System, both as to on-label and off-label uses. (FAC ¶ 98).

Relators allege that Defendant promoted the Precision Plus™ System beyond FDA-approved indications, and the provision of free services and other inducements to physicians. (FAC ¶ 88). Relators allege the Defendant had mandatory meetings at Boston Scientific's Valencia, California headquarters where annual off-label presentations were given. These presentations began at least as early as 2005, and annually through at least 2008. These mandatory meetings for Boston Scientific employees were attended by Boston Scientific's senior management, including Michael Onuscheck, Boston Scientific's Vice President of Sales and Marketing for Boston Scientific's Pain Management business (who led the commercial launch of the Precision™ Spinal Cord Stimulation System), John Hernandez, Wendy Chan, Richard Garcia, Boston Scientific staff, patient speakers, physician speakers, sales representatives as well as reimbursement specialists. (FAC ¶ 33).

Relators also allege that the Company paid speakers to promote the Precision Plus™ system for off-label uses, and provide the example of Michael Roman ("Roman") a paid spokesperson for the Precision Plus™ System, who spoke nationally on the use of the Precision Plus™ System for his phantom leg pain. Roman is a partial amputee, and experienced pain associated with phantom limb pain, a use of the Precision Plus™ not approved by the FDA. (FAC ¶ 94).

Defendant provided free services to prescribing physicians to induce use of the SCS. (FAC ¶ 98). Moreover, Relators link the kickbacks to the false certification of compliance with the Anti-Kickback Act ("AKA").[17] (FAC ¶ 99). Compliance with the AKA is a pre-condition of payment by the government, based on Defendant's execution of Form 855, the DME supplier form (described, *supra*).

Relators allege that to participate in the Medicare program, DME suppliers enter into agreements with CMS in which the supplier agrees to conform to all applicable statutory and regulatory requirements for reimbursement from Medicare. For DME suppliers like Boston Scientific, a CMS Form 855 (or equivalent) is completed. At all relevant times, Boston Scientific was a certified supplier which applied for Medicare enrollment by completing a Form CMS-855. The CMS-855 contains a certification of compliance with law, which further notified Boston Scientific that lawful compliance is a condition of payment by Medicare. (FAC ¶ 100).

Relators further allege, as noted above, that the Form 855 requires suppliers like Defendant to abide by applicable Medicare laws, regulations and program instructions and that the payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal AKA and the Stark

[17] 42 U.S.C. §1320a-7b.

law), and on the provider's compliance with all applicable conditions of participation in Medicare. (FAC ¶ 100).

Finally, as a result of Defendant's kickbacks, false claims were submitted to the government for claims tainted by illegal kickbacks, rendering these tainted claims ineligible for reimbursement.

The Court of Appeals has stated that compliance with the AKA is material to the Government's decision to make payment under the Medicare and Medicaid programs. U*nited States ex. rel, Kosenke v. Carlisle HMA, Inc.*, 544 F.3d 88, 94 (3rd Cir. 2009)("falsely certifying compliance with . . . Anti-Kickback Act[] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA"). Moreover, *United States ex. rel. Quinn v. Omni Care*, 382 F.3d 432, 438 (3d Cir. 2004) makes clear that a claim for payment may be "false or fraudulent" under § 3729(a)(1) whether or not it is "factually false" and whether or not it falls within the § 3729(a)(2) certification-related provision. Thus, defendant who employs deceit, concealment or intentional nondisclosure for the purpose of extracting funds that it would otherwise not have been able to obtain cannot escape liability under the FCA because the claim was technically true. *See, United States ex. rel. Monahan v. Robert Wood Johnson University Hospital*, 2009 U.S. Dist. LEXIS 38898 (D.N.J. 2009)(the defendants claims could be fraudulent

because the Government had "pled facts which demonstrate non-disclosure and intentional misrepresentation, which are the hallmarks of 'fraud'").

In *United States ex. rel. Zimmer*, 386 F.3d 235 (3d Cir. 2004) the Court held that a medical device company which marketed orthopedic implants, which knowingly caused a hospital to submit a false certification of compliance in Medicare form HCFA-2552 by payment of kickbacks, can be held liable under the FCA. Here, Relators allege that Defendant itself falsely certified compliance on Medicare Supplier Form 855, and on each and every falsified CMS-1500 form it submitted. (*See* FAC ¶¶ 100-101).

Under the "express false certification" theory, an entity is liable under the FCA for falsely certifying, as Relators allege, that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds. *See United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009).

Accordingly, here, where claims were submitted to the government tainted by illegal kickbacks, they were ineligible for payment due to lack of compliance with the AKA. Consistent with the case law as described above, the FAC adequately alleges that Defendant provided illegal kickbacks to physicians as part of its marketing scheme for the SCS system, but also that compliance with the Anti-Kickback statute is a condition of payment.

VII. RELATORS HAVE SUFFICIENTLY ALLEGED RETALIATION CLAIMS

Defendant argues that Relators do not allege a viable retaliation claim because they merely complained to their supervisors about Boston Scientific's billing practices. (Def. Br. 32-33). Like Boston Scientific's other arguments, this assertion ignores Relators' detailed allegations that describe their efforts to put Boston Scientific on notice about their investigation of fraudulent claims. Read in its entirety, the complaint more than sufficiently states that the Relators were engaged in protected activity under § 3730(h).

Relators allege that they were trained and directed by Boston Scientific to assist in its fraudulent billing scheme and that after continually complaining about Boston Scientifics' "unlawful billing practices to their supervisors", Relators were disciplined for continually pointing out the Medicare billing fraud that Relators were forced to engage in as a condition of their employment. (FAC ¶¶ 143-44). Relators allege that they made "multiple complaints "about the "fraudulent billing conduct." (FAC ¶¶ 146-147). In particular, Relator Bahnsen questioned the use of code 724.2 in absence of any diagnosis, and told her trainer that such conduct was "illegal." (FAC ¶ 148). The response Bahnsen received was that she should "get used to it," as this was the best way to ensure prompt Medicare payment to deal with the thousands of backlogged invoices. (FAC ¶ 149). The Relators were also trained to forget contacting doctors to obtain orders and diagnosis code, and

routinely used code 724.2, which a trainer wrote on a pink post-it note and stuck it on Relator Bahnsen's computer screen. (FAC ¶ 150-151).

In mid-June 2009, Relator Bahnsen became increasingly troubled by the fraudulent billing practices and brought her collections manager copies of the Medicare billing guidelines and examples of "falsified claims." (FAC ¶ 154). At a meeting, she complained that the policy of falsifying CMS-1500 forms was "illegal," which was met by a supervisor taking the unsigned 1500 claims forms and returning them that Relator Bahnsen "signed." (FAC ¶¶ 155-156). Thereafter, both Relators were banned from group meetings.

Based upon the Relators' internal complaints about the billing fraud, Boston Scientific conducted its own internal investigation by its Compliance Officer. This investigation also included interviews by outside counsel hired by Boston Scientific. (FAC ¶ 145). Boston Scientific was informed that Relator Bahnsen intended to file a "whistleblower case," and shortly thereafter was terminated. (FAC ¶ 161).

Boston Scientific's characterization of these allegations as mere complaints about "billing practices" is disingenuous. In this circuit and others, protected activity under § 3730(h) can include "internal reporting and investigation of an employer's false or fraudulent claims." *Hutchins v. Wilentz*, 253 F.3d 176, 187 (3rd Cir. 2001); *See also United States ex rel. Marlar DBWXTY-12, LLC*, 525 F.3d

439, 451 (6th Cir. 2008) (complaint about fraud perpetrated on a government sufficient to constitute protected conduct); *Schuhardt v. Washington Univ.*, 390 F.3d 563, 568-69 (8th Cir. 2004) (finding employee's complaint that billing practice was "fraudulent" and "illegal" provided sufficient notice of protected activity); *Yesudian v. Howard University*, 153 F.3d 731 (D.C. Cir. 1998); *Childree v. UAP/AGGA CHEN Inc*., 92 F.3d 140, 1145 (11th Cir. 1996); *United States ex rel. Cooper v. Gentiva Health Services, Inc*., 2003 U.S. Dist. LEXIS 20690, at *17 (W.D. Pa. Nov. 4, 2003) (concluding direct call to corporation's compliance hotline was protected activity); *Mann v. Heckler and Koch Defense, Inc*., 2008 WL 4551104 (E.D. Va. Nov. 7, 2008) (Plaintiff's informing employer of his belief that late delivery of rifle parts after bid submission deadline was fraudulent was protected conduct).[18]

[18] Boston Scientific asserts that Relator Fuentes fails to provide sufficient detail about her whistleblowing complaints to put it on notice of her protected activity. Def. Br. at 33. But, as noted above, Relators, including Fuentes, made multiple complaints about Defendant's "fraudulent billing." (FAC ¶¶ 146-147). Rather than modify its fraudulent billing practices, Relators were trained to forget about contacting doctors to obtain orders and diagnosis codes, and just routinely used code 724.2. (FAC ¶ 151). Like Relator Bahnsen, Fuentes was disciplined for continually pointing out the Medicare billing fraud and after their complaints escalated, was interviewed by Defendant's Compliance Officer and outside counsel. (FAC ¶¶ 144-145). Eventually Fuentes was cut off from computer access and was forced to work in an oppressive work-place. (FAC ¶ 162). Contrary to Boston Scientific's suggestion, these allegations amount to more than "mere dissatisfaction with ones treatment on the job" and at the very least, constitute internal complaints about fraudulent billing practices, which, under the law, put Boston Scientific on notice of her protected conduct.

As the Court in the *United States ex rel. Eberhardt v. Integrated Design and Construction, Inc*., 167 F.3d 861 (4th Cir. 1999) stated:

> Such notice can be accomplished by expressly stating an attention to bring a *qui tam* suit, but it may also be accomplished by any action which a fact finder reasonably could conclude would put the employer on notice that litigation is a reasonable possibility. Such actions would include, but are not limited to, characterizing the employers conduct as illegal or fraudulent, or recommending that legal counsel become involved. These types of actions are sufficient because they let the employer know, regardless of whether the employee's job duties include investigating potential fraud, that litigation is a reasonable possibility.

Here, not only did the Relators complain to their supervisors about "fraudulent billing," they went so far as to state that the use of Code 724.2 was "illegal." The Relators refused to participate in the policy of falsifying the CMS-1500 forms and in response to the Relators continuing complaints, Boston Scientific conducted an internal investigation, which included interviews of Relators by outside counsel hired by Boston Scientific.[19] These facts are more than sufficient to establish that the Relators engaged in protected activity.

[19] Divorcing itself from the allegations of the complaint, Boston Scientific claims that the factual allegation that Boston Scientific was informed that Bahnsen intended to file a whistleblower case, and shortly thereafter was terminated (FAC at ¶ 161) is "vague and conclusory." (Def. Br. at 35). This allegation establishes not only that Boston Scientific was put on notice of Relator Bahnsen's protected activity, but establishes the plausible connection between her protected activity and eventual termination. Boston Scientific's assertion that this allegation is insufficiently pled is baseless, as the allegations must only meet the *Iqbal* test of plausibility; not Rule 9(b)'s specificity requirement. *Mendiondo v. Centinela Hosp.*

VIII. RELATORS ALLEGE VIABLE STATE LAW CLAIMS

Defendant again misreads Relators' allegations by blithely asserting that Relators have not provided the factual basis for their State law claims. The Relators allege that the false and fraudulent claims alleged in the FAC similarly violate the corresponding State *qui tam* statutes (*See e.g.* FAC ¶ 2, Counts IV-XXIX), which are modeled on the Federal FCA. Given the substantive similarities between the Federal FCA and the State FCA's, State FCA's are construed consistently with the Federal FCA. *See e.g. New York v. Amgen, Inc.*, 652 F.3d 103, 109 (1st Cir. 2011) (New York FCA may be construed consistently with the Federal Act.); *United States ex rel. Humphrey v. Franklin-Williamson Human Services, Inc.*, 189 F.Supp.2d 862, 867 (S.D.Ill. 2002) (Illinois' version of the FCA should be interpreted consistently with the FCA). Relators' allegations and claims in the FAC apply with equal force to each State FCA, and should not be dismissed.

IX. CONCLUSION

Boston Scientific's Motion to Dismiss is premised on a fundamental misreading of Relators' detailed factual allegations, a mischaracterization of Medicare's medical necessity requirements, while ignoring the stringent legal and regulatory requirements Medicare imposes on medical equipment suppliers as a condition of Medicare payment. When Relators brought the unlawful conduct to

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Med. Ctr., 521 F.3d 1097, 1103 (9th Cir. 2008)(applying Rule 8 lower pleading standard to FCA retaliation claim).

Boston Scientific's attention in an effort to stop False Claims Act violations, instead of correcting, or even addressing Relators' complaints, Boston Scientific chose to silence the whistleblowers. Boston Scientific's motion should be denied in its entirety.

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